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(54) Balloon catheter and method for manufacturing such a catheter

(57) The invention relates to a method for the manufacture of a balloon catheter. It comprises the providing of a piece of tube-like basic material, the manufacturing of a balloon member and the connecting of the balloon member with the basic material. The manufacturing of the balloon member comprises the providing of a mould which in its turn is provided with a mould cavity corresponding to an intended expanded form of the balloon member, turning at opposite ends into securing elements for the purpose of securing opposite end sections of a piece tube-like semimanufacture in the mould cavity, the receiving of the semimanufacture in the mould, the heating of the semimanufacture, the generating of a pressure difference between the inside and the outside of the semimanufacture as a result of which it expands into the balloon member arranged against the walls of the mould cavity. On being received in the mould, the end sections of the semimanufacture are turned over an angle in relation to each other.

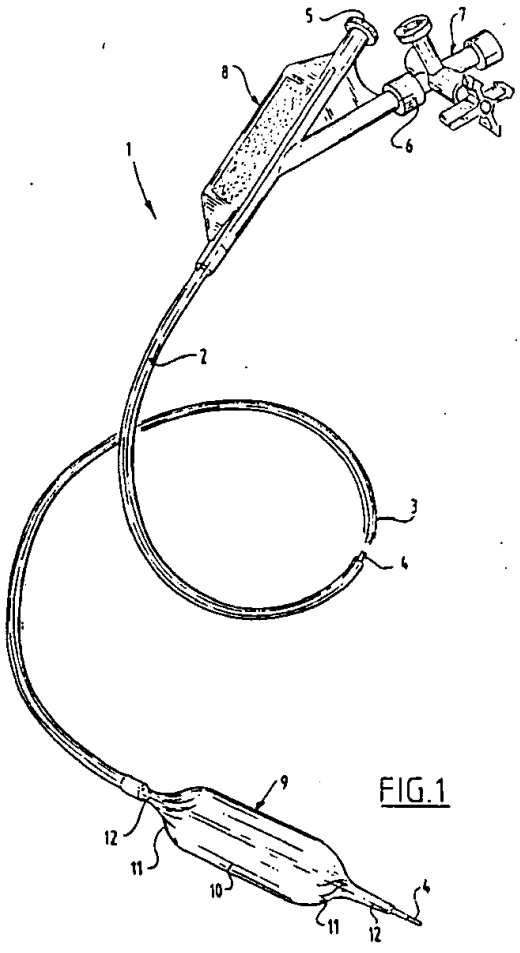

FIG.1

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Description

The invention relates to a method for manufacturing a balloon catheter, in particular a balloon catheter with a very large balloon, as is known from US patent application 4 906 244.

The balloon for such a balloon catheter is made up of a central section with on both sides transition sections to tube-like end sections. The balloon is usually manufactured by means of blow-moulding a piece of tube-like semimanufacture. The wall of the semimanufacture is relatively thick, so that sufficient material is available for the central section which is to be expanded.

In the transition sections the wall thickness decreases from that of the tube-like end section to that of the expanded central section. The wall of the transition section close to the end section is consequently still relatively thick, which considerably impedes the folding of the balloon into a small diameter. This folding into a small diameter is desirable however, in order to be able to introduce the balloon catheter properly into a patient.

What is more, the wall thickness in the transition section does, in general, not decrease uniformly. There will be sections with a relatively thick wall separated from each other by sections with a relatively thin wall. This further impedes the folding of the balloon into a small diameter.

The object of the invention is to provide a method for manufacturing such a balloon catheter, resulting in a balloon which can be folded into a small diameter properly.

This aim is achieved with the method as characterised in claim 1. By receiving the semi-manufactured product thus twisted in the mould, ridges of material extending fan-shaped from the end section are formed on expansion in the transition section of the balloon member, of which the walls are thicker than those of the intermediate sections. As a result the transition section can be folded together very easily into a small diameter.

The tube-like semimanufacture is preferably manufactured by extrusion and is pre-stretched before it is received in the mould. As a result the material will obtain the optimum properties required for the ensuing blow-moulding process.

An advantageous further development is characterised in claim 3. By carrying out the blow-moulding process in two stages, an optimum distribution of material can be achieved in the end product.

With the measures as set out in claim 4, a suitable number of evenly distributed fan-shaped ridges of material is obtained. There are approximately ten of them.

A further advantageous development is characterised in claim 5. As a result the ridges of material stretch out fan-shaped in a pattern of spirals extending in a clockwise direction. The introduction of the catheter into the patient and the removal thereof later on, can be facilitated by rotating the catheter round its longitudinal axis. The ridges of material extending in the folded state in a helical pattern support, on rotation, the movement in a longitudinal direction by a screw action.

The invention also relates to and provides a balloon catheter manufactured in accordance with the method as characterised in claim 6.

An advantageous small diameter of the balloon member can be achieved with the measures as set out in claim 7. A very gradual transition without bulges is achieved from the end sections to the folded central section.

Additional advantageous properties and advantages of the invention will become apparent when reading the following description of an example of an embodiment with reference to the attached drawings.

Figure 1 shows a catheter manufactured with the method according to the invention in a partly broken away perspective view,

Figure 2 illustrates schematically one step of the method according to the invention,

Figure 3 is a large-scale drawing of the balloon member of the catheter of figure 1,

Figure 4 shows a frontal view of the balloon member of figure 3 in the direction as indicated by arrow IV,

Figure 5 shows the balloon member of figure 3 in the folded state,

Figure 6 shows a cross-section along the line VI-VI of figure 5.

The catheter 1 shown in figure 1 comprises a tube-like basic body 2 which has been assembled from an outer tube-like element 3, in a central lumen whereof an inner tube-like element 4 has been received. The tube-like element 4 also comprises a lumen.

At the proximal end of the catheter 1 a connecting element 8 has been arranged. This connecting element 8 has two connections 5 and 6. The connection 5 is connected with the lumen of the inner tube-like element 4 and the connection 6 is connected with the lumen of the outer tube-like element 3, that is to say, the channel with annular cross-section formed by the space not taken up by the inner tube-like element 4 inside the lumen of the outer tube-like element 3.

As can be seen in the figure, a tap 7, known as such, can be arranged to the connection 6.

At the distal end the catheter 1 is provided with a balloon member 9. This is a balloon with a very large diameter sometimes referred to as a "fatsy".

The balloon member 9 has an active central section 10 with on either side transition sections 11 turning into end sections 12.

The balloon member 9 has been manufactured in at least one step of the blow-moulding process by the method according to the invention. This step will be explained in greater detail with reference to figure 2.

In figure 2 a mould 15 has been illustrated schematically, comprising two mould sections 16, 17. In the mould sections 16 and 17 a mould cavity 18 has been

provided, the shape of which corresponds with that of an intended expanded form of the balloon member to be manufactured. At opposite ends this mould cavity 18 turns into securing elements 19. In the securing elements 19 the end sections 21 of a tube-like semimanufacture 20 are secured.

As is indicated by the arrows, the semimanufacture 20 is twisted before it is received in the mould 15. For this purpose the end sections 21 are turned over a certain angle in relation to each other. A suitable angle is one of 270°.

After receiving the semimanufacture 20 in the mould 15, a pressure difference between the inside and the outside of the semimanufacture 20 is generated in an obvious manner not explained in greater detail here, for instance by connecting the channel defined inside the semimanufacture 20 to a source of gas under pressure. At the same time the semimanufacture is heated to a temperature higher than its softening temperature, so that it will be "blown up". The inflated section of the semimanufacture 20 arranges itself against the wall of the mould cavity 18 and thus obtains the intended expanded form.

Next one can allow the semimanufacture to cool down, so that the expanded form is retained. Because of the flexibility of the material of which the semimanufacture has been made, which is a plastic material, the balloon member formed can be folded and expanded again afterwards by increasing the pressure inside.

Figure 3 is a large-scale drawing of the balloon member thus formed. Because the semimanufacture 20 has been received in the mould 15 in the twisted manner described above, ridges of material 22 have been formed in the transition sections 11 extending fan-shaped from the end sections 12. The ridges of material 22 are relatively thick, whereas the material in between is stretched out. The ridges of material 22 have been shown once more in figure 4 for the sake of clarity.

The ridges of material 22 can, to a certain extent, be compared with the spokes of an umbrella. They can fold against each other, whereby the thinner material inbetween is folded into pleads. Thus, in folded state, a small diameter can be achieved.

This folded state is illustrated in the figures 5 up to and including 7.

As can be seen in the figures 5 and 6, the central section 10 and the transition sections 11 are folded in pleads against the inner tube-like element 4 of the basic body 2. The folds 24 fit closely together and substantially coincide with the fan-shaped ridges of material 22.

As can be seen in figure 5 as well, the outer tube-like element 3 of the basic body 2 is shorter than the inner tube-like element 4. The relatively proximal end section 12 of the balloon member 9 is connected with the end of the outer tube-like element 3, whereas the relatively distal end section 12 of the balloon member 9 is connected with the inner tube-like element 4. The inside of the balloon member 9 is therefore connected via the remaining channel with annular cross-section inside the outer tube-like element 3 with the connection 5 of the connecting member 8. By supplying via this connection a gas or liquid under pressure, the balloon 9 can be unfolded into its expanded form. This occurs following introduction of the catheter into a patient for the purpose of dilation or occlusion of a blood vessel.

Introduction occurs in the usual manner via an introduction sheath 26 which has been illustrated schematically in figure 7. This introduction sheath 26 can have a relatively small inside diameter, as the balloon member 9 can be folded into a small diameter and because no bulges are formed at the transition sections as a result of unevenly distributed basic material.

As a result of the ridges of material extending in a fan-shaped manner and the closely fitting folds, sections with a helically shaped profile are formed on either side of the balloon member. By rotating the catheter in a suitable manner, as indicated by arrow 27, a certain force 28 can be generated by screw action, which facilitates the introduction of the catheter. Also the removal of the catheter can take place smoothly by applying a correct rotation.

Although the method according to the invention is explained with reference to figure 2, in which a balloon member is formed in one single blow-moulding step, it is also possible to achieve the same in more steps. A first initiation can for example be carried out in the form of a limited expansion in order to obtain a second semimanufacture with a suitable material distribution. This second semimanufacture can then be expanded in a second blow-moulding step to obtain the intended ultimate form. In that case the suitable material distribution is achieved during the first step by the right choice of mould cavity of the mould in which this step is performed.

Claims

1. Method for manufacturing a balloon catheter, comprising the providing of a piece of tube-like basic material, the manufacturing of a balloon member and the connecting of the balloon member with the basic material, wherein the manufacturing of the balloon member comprises the providing of a mould which in its turn has been provided with a mould cavity corresponding to an intended expanded form of the balloon member, turning at opposite ends into securing elements for the purpose of securing opposite end sections of a piece of tube-like semimanufacture inside the mould cavity, the receiving of the semimanufacture in the mould, the heating of the semimanufacture, the generating of a pressure difference between the inside and the outside of the semimanufacture as a result of which it expands into the balloon member arranged against the walls of the mould cavity, wherein the end sections of the semimanufacture on being received in the mould are turned over an angle in relation to each other.

2. Method as claimed in claim 1, wherein the tube-like semimanufacture is manufactured by means of extrusion and is pre-stretched before being received in the mould.

3. Method as claimed in one of the previous claims, wherein the intended expanded form is an intermediate form, and the heated, expanded balloon member is transferred to a second mould in which it is given its definite shape, and the cooling down of the balloon member.

4. Method as claimed in one of the previous claims, wherein the end sections are turned substantially over an angle of 270° in relation to each other.

5. Method as claimed in one of the previous claims, wherein the end sections are turned in such a direction, that the semimanufacture is twisted in the direction of a helix extending clockwise.

6. Balloon catheter manufactured with the method according to one of the previous claims, wherein the balloon member comprises a central section with on either side transition sections turning into tube-like end sections, of which at least one comprises ridges of material extending fan-shaped from the end section.

7. Balloon catheter as claimed in claim 6, wherein the central section and the transition sections are folded in pleads against the basic body and wherein the pleads substantially coincide with the fan-shaped ridges of material.

8. Balloon catheter as claimed in claim 6 or 7, wherein the ridges of material are substantially evenly distributed around the circumference of the transition section.

9. Balloon catheter according to one of the claims 6-8, wherein the transition section comprises between 5 and 15 ridges of material.

10. Balloon catheter as claimed in claim 9, wherein the transition section comprises some 10 ridges of material.

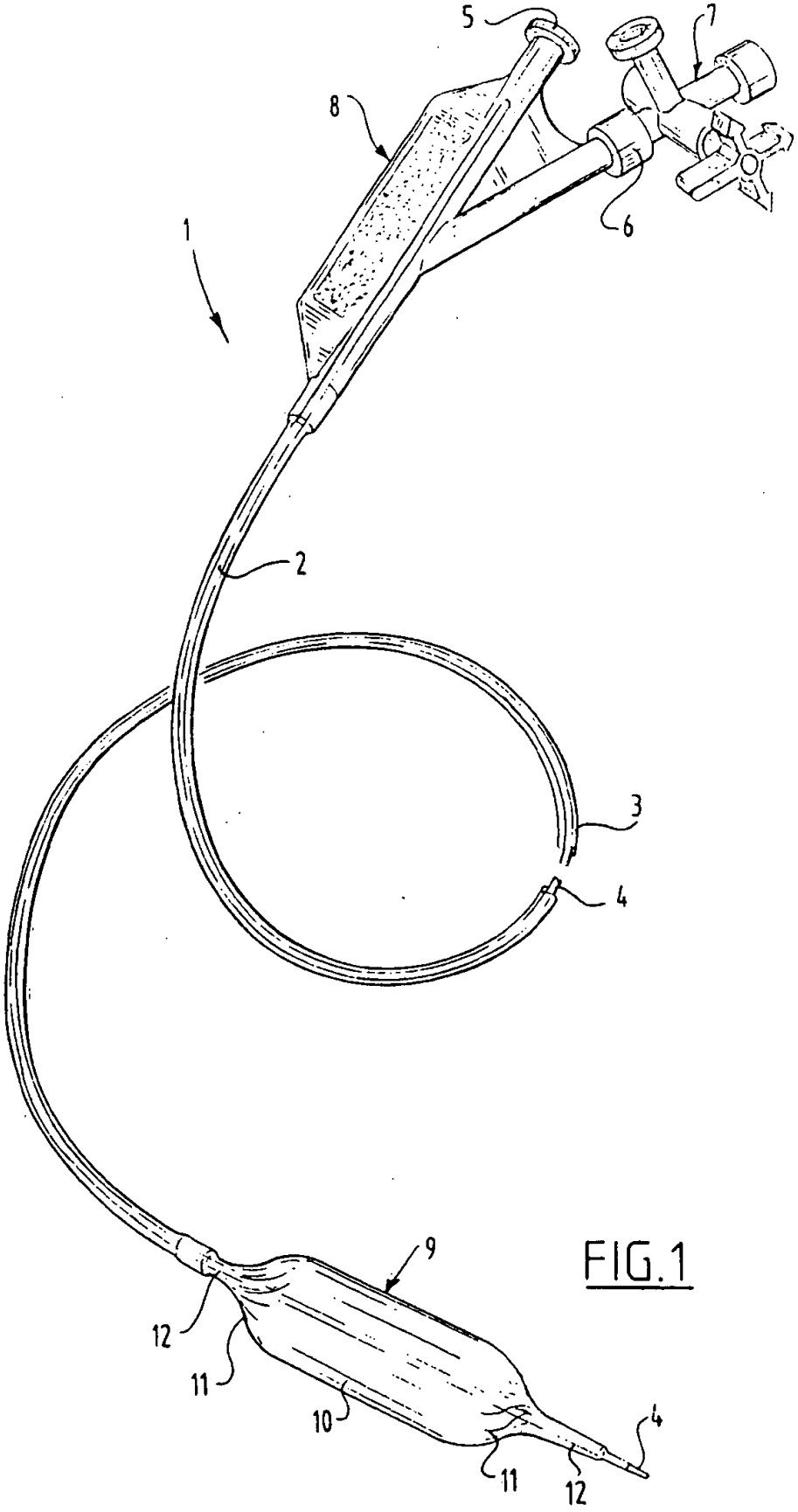


FIG.1

FIG.2

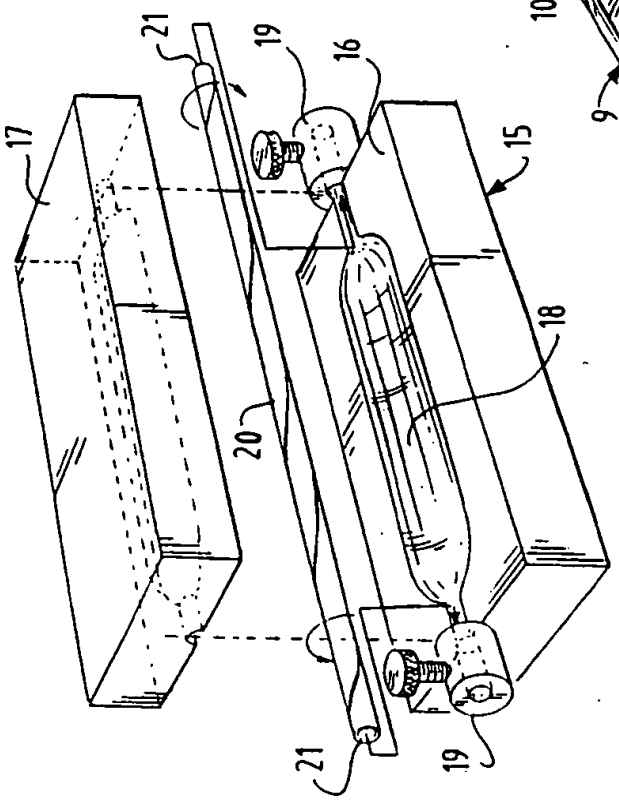
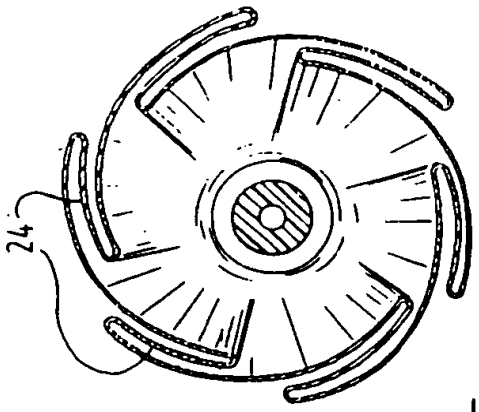


FIG.5

FIG.6



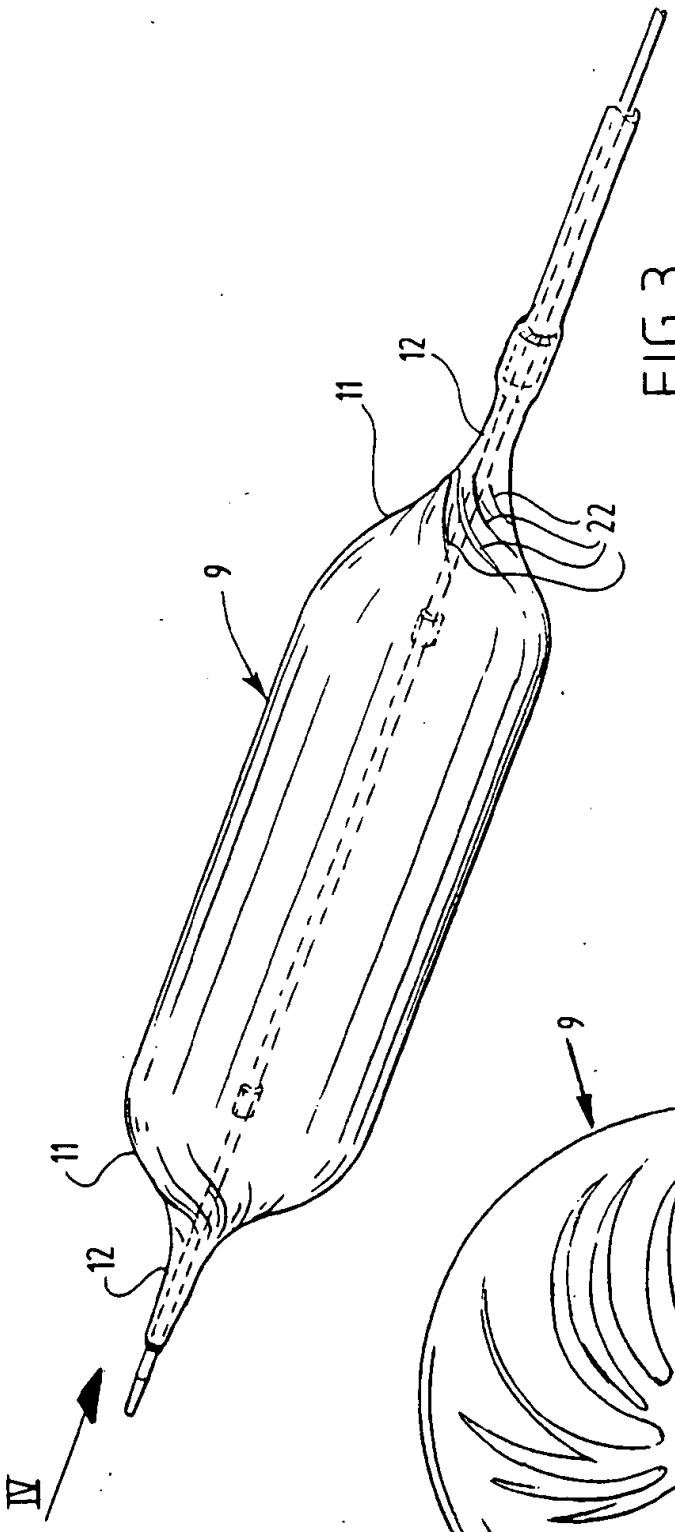


FIG.3

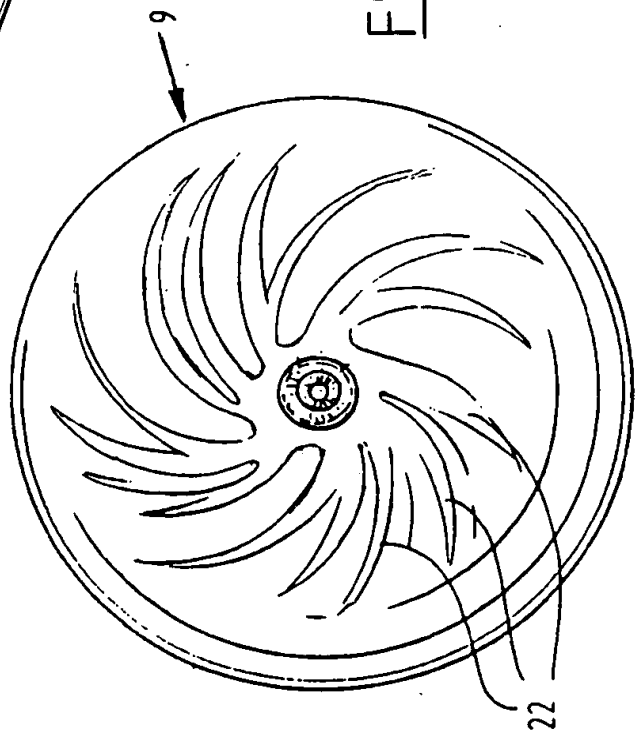


FIG.4

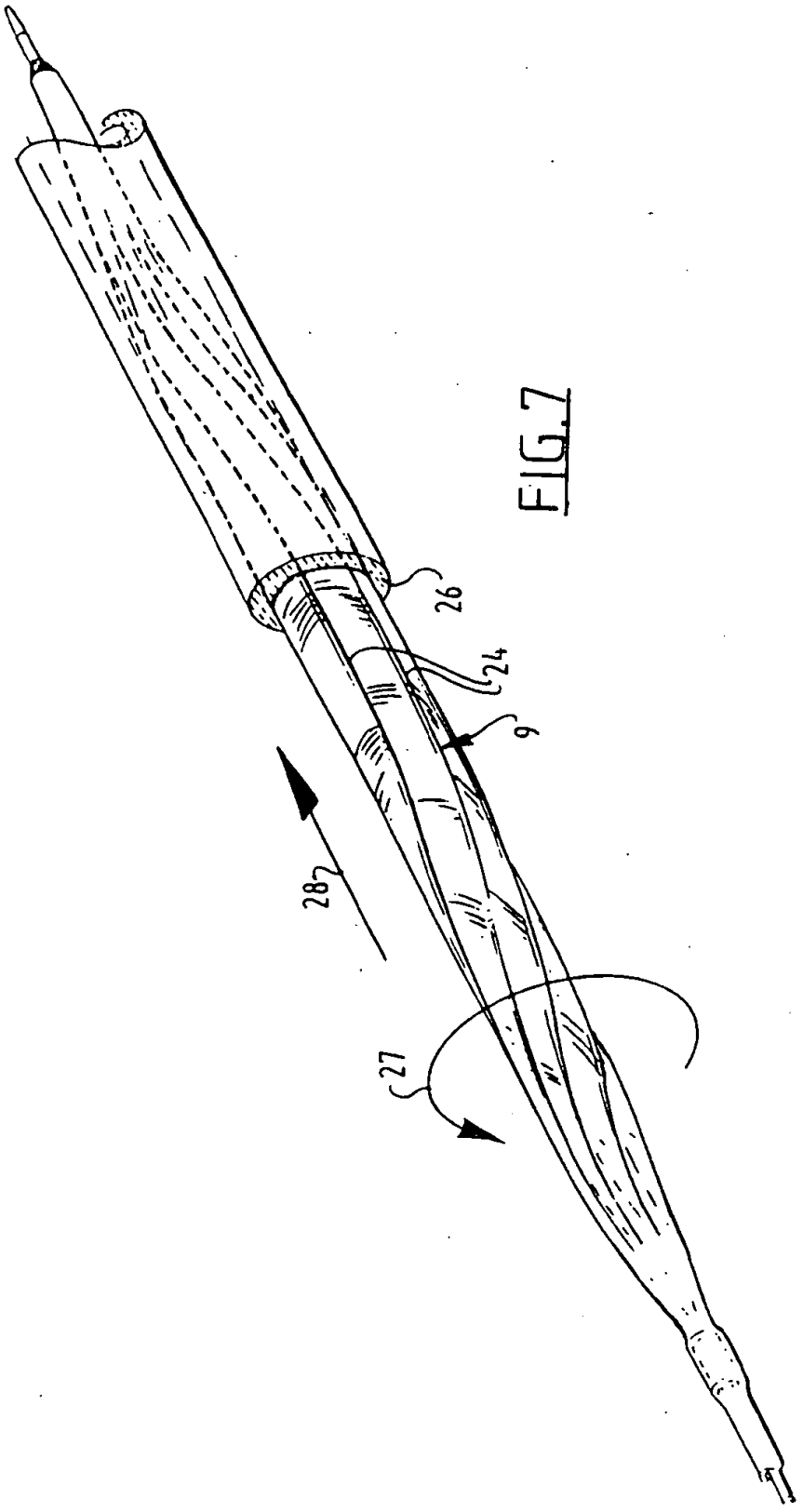


FIG.7

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EUROPEAN SEARCH REPORT

Application Number
EP 96 20 0357

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US-A-4 935 190 (TENNERSTEDT) 19 June 1990 * column 5, line 33 - column 6, line 65; figure 3 *	1,2	A61M25/00
A	EP-A-0 439 202 (CORDIS) 31 July 1991 * abstract; figures 1-3 *	1	
A	EP-A-0 376 451 (BARD) 4 July 1990 * column 7, line 12 - line 39; figures 7,8 *	1	
A	EP-A-0 304 258 (BARD) 22 February 1989 * column 7, line 6 - column 8, line 22; figures *	1	
A	US-A-5 015 230 (MARTIN) 14 May 1991 * column 4, line 54 - column 6, line 23; figures 7,13,14 *	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M
B29C

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	6 June 1996	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

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